

a therapeutic amount of glucocorticoid, an antibacterial agent and benzoyl peroxide.

29. (New) A method of preventing or treating pseudofolliculitis barbae comprising applying a shaving preparation consisting essentially of a therapeutic amount of a glucocorticoid, propylene glycol and white lotion NF to a skin area to be shaved, prior to shaving, after shaving, between shaves.

30. (New) A method of hindering the appearance of pseudofolliculitis barbae comprising applying a shaving preparation wherein the active ingredient consists essentially of a therapeutic amount of a glucocorticoid to a skin area to be shaved, prior to shaving, after shaving, or between shaves.

#### REMARKS

Claims 13, 17, 18, 19 and 23 have been amended. Support for claims 13, 17, 18, 19 and 23 is found at page 2, paragraph 8 through page 3, paragraph 10 of Applicant's specification. New claims 27-28 have been added. Support for claims 27-28 is found at page 3, paragraph 11 and page 4, paragraph 14 of Applicant's specification. Accordingly, claims 13, and 17-28 are now pending in the application. Reconsideration and allowance of the above-referenced application is respectfully requested.

The Examiner has rejected claims 1-26 under 35 U.S.C. 112, first paragraph, asserting that the specification does not reasonably provide enablement for prevention of pseudofolliculitis barbae. The Examiner has suggested that "[i]n claiming prevention one is suggesting a 100% cure rate . . . [and that] Just as there is no cure for cancer, applicant's specification does not support claiming a cure or prevention of pseudofolliculitis." Applicant respectfully disagrees.

By prevention, the Applicant means that the method provides an obstacle or hindrance to the creation of the skin condition. As demonstrated in Example 9 of the Application, after two weeks of treatment, the use of the claimed composition resulted in the reduction of the number of lesions in the affected area by about 75 to 80%. The treatment consisted of the application of the shaving preparation to the affected area immediately prior to shaving one to two times per week. Thus, the shaving preparation not only treated the pseudofolliculitis barbae, but it also prevented the formation of lesions caused by shaving. Accordingly, Applicant respectfully traverses this rejection.

The Examiner has stated that "[i]n claim 23 glucocorticoid is the essential shaving cream element," and that with respect to the optional agents, separate independent claims appear needed. Accordingly, Applicant has amended claim 23 to claim a cream consisting essentially of a therapeutic amount of glucocorticoid and has added new independent claims 27 and 28 to include the additional agents. Accordingly, claims 23-28 are in allowable condition, and Applicant respectfully requests issue of allowance of these claims.

The Examiner has rejected claims 1-3, 5, 9 and 10 under 35 U.S.C. 102(b) as anticipated by McGinity U.S. Patent No. 3,898,330; and claims 1-3, 5, 6, 8-10 under 35 U.S.C. 102(e) as anticipated by Rico U.S. Patent No. 6,375,942. As Applicant has canceled claims 1-12 without prejudice, the rejections over McGinity and Rico are now moot.

The Examiner has rejected claims 13, 17-19, 21 and 22 under 35 U.S.C. 102(b) as anticipated by Moore U.S. Patent No. 4,944,939. Applicant has amended claims 13, and 17-19 to a method comprising a shaving preparation consisting essentially of glucocorticoid.

Accordingly, Applicant submits that pending claims 13, 17-19, 21 and 22 are not anticipated by Moore.

The present invention is directed to a method for treatment and prevention of pseudofolliculitis barbae by applying a shaving preparation wherein the active ingredient consists essentially of glucocorticoid. Moore discloses a shaving preparation containing salicylic acid, a glucocorticoid, and sulfur as the active ingredients for use in the treatment and prevention of PFB. The salicylic acid is used to cause thinning of the upper layer of the skin in order to help free ingrown hairs and also to reduce the likelihood that other hairs will be trapped by shaving. The glucocorticoid is used to counter inflammation, and sulfur is used to counter infection. Moore does not teach the application of a composition consisting essentially of glucocorticoid to a skin area to be shaved prior to shaving, after shaving and in between shaves to treat and prevent pseudofolliculitis barbae. In fact, Moore teaches that if the glucocorticoid is used separately from the other two ingredients, it should be applied 8 to 12 hours before shaving, and any trapped hairs are then lifted mechanically with the tool illustrated in the patent. After removing the ingrown hairs mechanically, the beard is then wetted with a solution of propylene glycol and water, and a conventional shaving foam or soap is used for shaving. After shaving, the vehicle with the salicylic acid and sulfur is applied and if the ingrown hair problems are severe, the glucocorticoid can be applied after shaving as well.

Claims 13, 17-19 and 21 stand rejected under 35 U.S.C. 102(e) as anticipated by Ortiz et al. U.S. Patent No. 6,352,691. Applicant has amended claims 13, and 17-19 to a method comprising a shaving preparation wherein the active ingredient consists essentially of

glucocorticoid. Accordingly, Applicant submits that pending claims 13, 17-19, 21 are not anticipated by Ortiz.

Ortiz is directed to an after-shave care lotion, and a method for reducing inflammation and irritation associated with pseudofolliculitis using such composition, wherein the composition comprises several active ingredients, including aloe, vitamin C, vitamin E, and hydrocortisone acetate. According to Ortiz, each of these ingredients serves a different function relating to reducing inflammation and irritation, or nourishing and restoring the skin. The aloe extract is used for its known moisturizing and moisture balancing properties, the vitamin C is used for the production of collagen, vitamin E is used to protect cellular membranes from oxidative destruction by reducing free radical membrane damage, and the hydrocortisone acetate is employed as an anti-inflammatory agent. Ortiz further provides that the described after-shave care lotion should be applied once, immediately following shaving, and that multiple applications within a single day are not recommended.

#### CONCLUSION

For the reasons stated above, Applicant believes that the subject application is now in condition for allowance and respectfully request such favorable action. The Examiner is invited to contact the undersigned at the telephone number below if he believes that a discussion would help advance the progress of this application.



PATENT  
Serial No. 09/875,198  
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The Commissioner is authorized to charge any additional fees or credit any  
overpayments under 37 C.F.R. §§ 1.16 and 1.17 to Deposit Account No. 11-0600.

Respectfully submitted,

Dated: December 24, 2002

A handwritten signature in black ink, appearing to read "Maria Luisa Palmese".

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**Marked-up version of amended claims**

13. (Amended) A method of preventing or treating pseudofolliculitis barbae comprising applying a shaving preparation [comprising] wherein the active ingredient consists essentially of a therapeutic amount of a glucocorticoid to a skin area to be shaved, prior to shaving, after shaving, or between shaves.

17. (Amended) The method of claim 13, wherein the [shaving preparation comprises] glucocorticoid is provided in the amount of 0.025 to 2.5% by weight.

18. (Amended) The method of claim 13, wherein the [shaving preparation comprises] glucocorticoid is selected from the group consisting of hydrocortisone USP, hydrocortisone acetate, desonide and triamcinolone acetate.

19. (Amended) The method of claim 13, wherein the glucocorticoid is [shaving preparation comprises] hydrocortisone USP in the amount of about 1% by weight.

23. (Amended) A shaving cream to aid in the prevention and treatment of pseudofolliculitis barbae or ingrown hair wherein the active ingredient consists [consisting] essentially of a therapeutic amount of glucocorticoid [and optionally, at least one antibacterial agent, benzoyl peroxide or both as active ingredient].